

Notice of Allowability

Application No.

09/559,344

Examiner

Holly Schnizer

Applicant(s)

NEGRIER ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 7/22/04 and TD filed 9/13/04.
2. ☒ The allowed claim(s) is/are 1,3,4,9-12,15 and 16.
3. ☒ The drawings filed on 27 April 2000 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Amy Purcell on October 4, 2004.

The application has been amended as follows:

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IN THE SPECIFICATION:

On page 1, after the title of the invention and before "Subject of the Invention...", please insert the heading --INTRODUCTION--.

On page 3, line 1, before "The development of said DNA-construct was performed as follows:", please insert the following:

--BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the cloning of the GPIIb promoter into the pcDNA3 vector, thereby producing the pcDNA3-GPIIb construct.

Figure 2 demonstrates the generation of the pUT535-GPIIb construct, which contains a B-galactosidase reporter gene under the control of the truncated GPIIb promoter.

Figure 3 shows the transient B-galactosidase expression directed by the CMV and GPIIb promoter in HeLa cells (Panel A) and shows the transient B-galactosidase expression directed by the CMV and GPIIb promoter in HEL cells (Panel B).

Figure 4 shows the transient FIX production under CMV promoter control in HEL cells after PMA induction.

Figure 5 demonstrates transient production of FIX WT under CMV or GPIIb promoter control in HEL cells after PMA induction.

Figure 6 demonstrates FIX production under CMV promoter control in stably transfected HEL cells.

Figure 7 shows FIX production under GPIIb promoter control in stably transfected HEL cells.

Figure 8 demonstrates the correlation between FIX procoagulant activity and FIX antigen in the supernatants from HEL cells.

Figure 9a shows the stable expression of FIX (WT) in HEL cells without PMA induction. Figure 9b shows the stable expression of FIX (WT) in HEL cells with PMA induction.

Figure 10 demonstrates the ability of FIX (WT.I1) directed by the GPIIb promoter to increase FIX production in HEL cells.


Figure 11 shows the FIX coagulant activity in the supernatant of HEL cells transfected with GPIIb-FIX(WT.I1) construct after PMA induction.

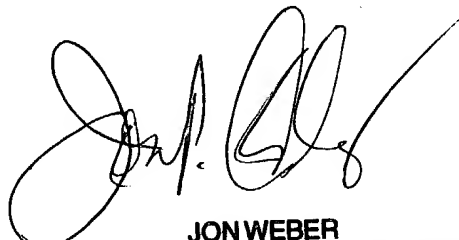
DETAILED DESCRIPTION—

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Holly Schnizer
October 4, 2004


JON WEBER
SUPERVISORY PATENT EXAMINER